

REMARKS

This Amendment amends claim 1. Claims 1-7 and 13-19 are pending, although claims 13-19 have been withdrawn from further consideration.

Entry of this Amendment is earnestly requested, as it is believed (1) to place the application in condition for allowance, (2) not to raise any new issue or require further search by the Examiner, (3) to be directly responsive to the Official Action, and (4) to place the application in even better form for appeal, should such appeal be necessary. This Amendment inserts the transitional phrase "comprising" into claim 1, thereby making even more clear the claimed method is directed to quantification of a clinical chemistry analyte. Applicants have previously traversed the prior art rejections based on this claim construction, and thus the Amendment does not raise any new issue or require further search by the Office.

This Amendment overcomes the 35 U.S.C. § 102(b) rejection of claims 1-10 and 12¹ over U.S. Patent No. 6,342,397 to Soini et al. Claim 1 has been amended to clearly require quantification of a clinical chemistry analyte, thus overcoming the Patent Office

¹Claims 8-12 have been previously canceled.

argument that "clinical chemistry analyte" occurs in the claim preamble and thus should not be given patentable weight.

The claimed diagnostic method of claims 1-7 comprises the quantification of a clinical chemistry analyte by excitation of a two-photon fluorescent compound or compounds and measurement of two-photon excited fluorescence. "Clinical chemistry analytes" are analytes which are measured by means of "clinical chemistry assays" (page 18, lines 4-5), which are quantitative assays which incorporate a chemical reaction, measured on a regular basis in clinical chemistry practice, excluding bioaffinity assays (page 18, lines 1-3). The specification defines "bioaffinity assays as all assays based on bioaffinity binding reactions, i.e., a reaction where bioaffinity complexes are formed. These bioaffinity assays include immunoassays and nucleic acid hybridization assays, but do not include assays which are based on enzyme-catalyzed chemical reactions or other reactions where covalent binding of compounds is changed (Specification, page 17, lines 2-26).

Soini et al. fails to disclose the clinical chemistry analyte feature of the claimed method. Instead, one of ordinary skill in the art would understand the clinical analytes disclosed in Soini et al. are all analytes quantified using immunoassays, i.e., assays

defined as *bioaffinity assays*, and would not consider these analytes clinical chemistry analytes.

Reconsideration and withdrawal of the anticipation rejection of claims 1-10 and 12 over U.S. Patent No. 6,342,397 to Soini et al. are respectfully requested.

The 35 U.S.C. § 103(a) rejection of canceled claim 9 over Soini et al. is traversed to the extent it may be applied against any of claims 1-7. As discussed above, a feature of the claimed diagnostic method is the quantification of a clinical chemistry analyte by excitation of a two-photon fluorescent compound or compounds and measurement of two-photon exited fluorescence. The clinical chemistry analytes are quantified by a method in which the analyte undergoes a chemical reaction or the analyte catalyses a chemical reaction. The inventors have discovered two-photon fluorescence technology surprisingly provides, when applied to quantification of clinical chemistry analytes, numerous advantages discussed in detail in the application (see page 22, line 15 to page 25, line 20).

Soini et al. fails to raise a prima facie case of obviousness against the claimed method because one of ordinary skill in the art is given no suggestion that clinical chemistry analytes could be

quantified by a method in which the analyte undergoes a chemical reaction or the analyte catalyses a chemical reaction using two-photon fluorescence technology. Instead, Soini et al. discloses quantification of clinical analytes using a bioaffinity assay which does not involve a chemical reaction of the analyte or a catalysis of a chemical reaction by the analyte.

Reconsideration and withdrawal of the obviousness rejection of claim 9 are earnestly requested.

This Amendment also overcomes the sole ground for maintaining the lack of unity objection. Claim 1 has been amended to unambiguously define a method for quantification of a clinical chemistry analyte. As discussed above, Soini et al. fails to disclose or suggest the claimed method. Instead, Soini et al. is limited to a biospecific bioaffinity assay which is excluded from the claimed method. Accordingly, Soini et al. does not destroy unity of invention among claims 1-7 and 13-19. Reconsideration and withdrawal of the restriction requirement, and examination of claims 13-19, are respectfully requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 1-7, and issuance of a Notice of Allowance directed to claims 1-7 and 13-19,

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AMENDMENT AFTER FINAL REJECTION

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are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

It is not believed any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

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